

Remarks

Applicants gratefully acknowledge that the rejection of Claims 1 and 2 under 35 U.S.C. 102(e) in view of Papsidero (US Patent No. 6, 306,653), has been withdrawn by the Examiner.

Claims 1 and 2 have been amended. Claim 6 has been cancelled. New claims 7 to 17 have been added.

Support for the amendments to the claims made herein may be found in the specification at the following pages; no new matter has been added:

<u>Claim 1</u>	<u>support at</u>
"polynucleotide"	page 3, lines 22-26, (last paragraph).
"highly stringent conditions"	page 12, line 24
"quantifying the level of said probe...in said sample"	page 5, lines 3-8; page 9, line 26 (last paragraph) to page 10, line 5 (first paragraph)

<u>Claim 2</u>	<u>support at</u>
"consecutive"	page 4, line 19;

Support for newly added claims 7 to 17 in their entirety can be found on page 4, lines 17-20; page 4, line 28 (last paragraph) to page 5, line 8 (first paragraph); page 11, lines 7-21; page 14, lines 1-17 and Example 5 on pages 16-17.

Claims 1, 2 and 6 have been rejected under 35 U.S.C. 112, first paragraph, for lack of enablement commensurate with the scope of the claims, specifically for overly broad probe scope. In response, Applicants have herein amended claims 1 and 2, to refer to highly stringent hybridization conditions, mentioning that the probe is for the detection of polynucleotides in a sample which encode a protein given by SEQ ID NO. 1 or fragments thereof. Highly stringent hybridization conditions are taught at page 4, lines 21-27 and page 12, lines 22-24. Newly added independent Claims 7, 12, and 164 also recite hybridization conditions performed under stringent or highly stringent conditions as taught by the specification and therefore comply with 35 USC 112 1st paragraph.

Claims 1, 2 and 6 are also currently rejected under 35 U.S.C. 112, first paragraph, for alleged failure to possess the claimed invention at time of filing, specifically, for the introduction by the Applicants of a generic concept of a control in Claim 1 that is unsupported by the specification. In response, Applicants have herein amended Claim 1 to eliminate this concept and have amended the claim to recite quantification of the presence or amount of polynucleotide in the sample as encompassed by the invention and taught throughout the specification.

Claims 1 and 2 also stand rejected under 102(e) as being anticipated by either Band (U.S. Patent No. 6,153,387) or Vogelstein et al. (U.S. Patent No. 5,527,676). Evidently, the Examiner is of the opinion that Applicant's description of the MEC probe in these claims is overly broad such that it can encompass the probes disclosed in these references (despite their being directed to entirely different proteins, NES1 and p53, respectively). In response, Applicants respectfully submit that as amended herewith, the probe of Claims 1 and 2 is of sufficient scope to avoid anticipation by the Band and Vogelstein references. As such, Applicants respectfully request that this rejection be withdrawn.

Claims 1, 2 and 6 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Band or Vogelstein in view of Coghlan (Coghlan et al., Analytical Biochemistry, 149:1-28, 1985). According to the Examiner, Band and Vogelstein theoretically teach a MEC probe (as broadly defined by Applicants) and when combined with the review of hybridization histochemistry provided in Coghlan, these references render Applicants invention *prima facie* obvious. In response, Applicants respectfully submit that, as discussed above, the amendments made herein to Claims 1 and 2 should remove Band and Vogelstein as anticipatory references. As such, in addition to the fact that Coghlan in no way teaches or suggests Applicant's MEC probe (let alone a method to detect a breast tumor using such a probe by *in situ* hybridization), the criteria necessary for a *prima facie* case of obviousness do not exist in this case and thus the Applicants respectfully request that the Examiner withdraw the 103(a) rejection.

Finally, for the reasons discussed above, Applicants submit newly added claims 7-17 are also not obvious over the references cited by the Examiner.

In view of the forgoing, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

If there are any fees due in connection with this communication, including any fees for a required extension of time, such an extension is requested and the Commissioner is authorized to charge the fees to Deposit Account No. 19-0134 in the name of Novartis.

Respectfully submitted,

Novartis Institutes for BioMedical Research
400 Technology Square
Cambridge, MA 02139
(617) 871-3356

Regina Bautista
Regina Bautista
Attorney for Applicants
Reg. No. 46,280

Date: August 20, 2003